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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: LAMICTAL DIRECT PURCHASER ANTITRUST LITIGATION	**Master File No. 12-995-WHW-MCA** **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**
LOUISIANA WHOLESALE DRUG CO., INC., on behalf of itself and all others similarly situated, **Plaintiff,** **V.** **SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHAMACEUTICALS** **Defendants.**	**Case No. 2:12-CV-00995-WHW-MCA**
KING DRUG COMPANY OF FLORENCE, INC., on behalf of itself and all others similarly situated, **Plaintiff,** **V.** **SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHAMACEUTICALS** **Defendants.**	**Case No. 2:12-CV-01607-WHW-MCA**

Plaintiffs Louisiana Wholesale Drug Co., Inc. ("LWD") and King Drug Company of Florence, Inc. ("King Drug") (collectively, "Plaintiffs"), maintaining their principal places of business at the addresses set forth in paragraphs 32 through 33, on behalf of themselves and all others similarly situated, for the Consolidated Amended Complaint against Defendants SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and its subsidiary Teva Pharmaceuticals USA, Inc. ("Teva USA") (jointly, "Teva") (all defendants collectively, "Defendants"), allege as follows based on: (a) personal knowledge; (b) the investigations of counsel, including review of various pleadings and rulings in *SmithKline Beecham Corp. v. Teva Pharmaceuticals USA, Inc.*, United States District Court, District of New Jersey, Nos. 02-cv-3779 and 02-cv-4537, and *Teva Pharmaceutical Industries Ltd., et. al v. SmithKline Beecham Corporation,* United States District Court, District of New Jersey, No. 08-cv-03706, discussed herein; and (c) information and belief.

I. NATURE OF THE ACTION

1. This antitrust action challenges Defendants' anticompetitive conduct that delayed generic competition in the markets for Lamictal Tablets and Lamictal Chewables, prescription drugs used to treat epilepsy, bipolar disorder and other medical conditions, and improperly manipulated the Hatch-Waxman Act to impede, rather than promote, generic competition as intended by the statute.

2. Under the Federal Food, Drug and Cosmetics Act of 1938, 21 U.S.C. §§ 301-392 ("FD&C Act"), a manufacturer that creates a new drug must obtain Food and Drug Administration ("FDA") approval to sell the new drug by filing a New Drug Application ("NDA") which includes, among other things, submission of clinical studies

concerning the safety and efficacy of the drug, as well as any information on applicable patents.

3. Recognizing the great savings available to purchasers by the presence of generic drugs, Congress in 1984 passed the "Hatch-Waxman Act" (officially called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)) ("Hatch-Waxman"), which amended the FD&C Act to facilitate and expedite the approval of generic drugs. Prior to these amendments, competitors seeking to sell a generic version of a brand name drug needed to go through the lengthy and costly process of filing their own NDA to obtain FDA approval. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by providing an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA"). A proposed generics' ANDA is not required to contain the same type of independent clinical studies to demonstrate safety and efficacy as contained in an NDA, but is allowed to make that showing by demonstrating that it is therapeutically and pharmaceutically equivalent to the corresponding brand drug.

4. "AB-rated" generic versions ("generics") of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. Specifically, the FDA has determined that an AB-rated generic product is therapeutically and pharmaceutically equivalent to the brand-name counterpart. This means that the generic version has the same active ingredient, strength, route of administration, and dosage form as the branded counterpart, and that the active ingredient of the generic drug remains in the bloodstream of the patient for the same relative amount of time in the same relative proportion as the branded drug.

5. The only material difference between generics and brand name drugs is their price. Generics are typically at least 30% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50-80% (or more) when there are multiple generic competitors on the market. As a result, generics constitute both: (a) an opportunity for drug purchasers and consumers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and profits of the manufacturer of a brand name drug facing generic competition. Because of the significant price savings from the use of generics, in most states the laws and regulations allow (and many states require) pharmacists to automatically substitute an AB-rated generic version of a drug for the brand name drug in most instances.

6. As part of the ANDA process a generic manufacturer must certify that the proposed generic drug does not violate any patents that claim the brand name drug, which are identified in an FDA publication called the Orange Book. When the ANDA applicant takes the position that any listed patent(s) is invalid or will not be infringed by the generic product, it must file a Paragraph IV certification. This is especially significant, because if a generic files a Paragraph IV certification, the brand-name manufacturer has the opportunity to slow down the approval process of the generic drug. If the patent owner files a patent infringement action within 45 days after receiving notice of the generic manufacturer's Paragraph IV certification, then the FDA is automatically enjoined from granting final approval to the ANDA until the earlier of either 30 months or the issuance of a district court decision that the patent is invalid, unenforceable, or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii).

7. The Hatch-Waxman Act encourages challenges to branded drug patents by granting the first Paragraph IV ANDA filer up to 180 days to exclusively market the generic version of the drug, during which time the FDA will not grant final approval to any other generic manufacturer's ANDA for the same generic drug. As explained in paragraph 12 below, the 180 days of marketing exclusivity granted to the first Paragraph IV ANDA filer is a significant and potentially highly profitable benefit.

8. Until an AB-rated generic enters the market, there is no drug or other product that price competes with the branded drug, and therefore, the brand manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its branded sales. Consequently, brand manufacturers have a strong incentive to engage in conduct, including the conduct alleged herein, to delay generic competition.

9. One tactic that brand manufacturers use to delay generic competition is to file a patent infringement suit against the generic (even if it is likely that the patent at issue is invalid, unenforceable, or not infringed) to trigger the automatic injunction that prevents the FDA from approving a generic ANDA for up to 30 months. Then, upon recognizing the significant risk that the patent infringement claims will not succeed, the branded manufacturer will give the generic manufacturer significant financial inducements to accept a settlement in which the generic agrees to stay off the market for a much longer time than the strength of the patent warrants. In such instances, the generic's agreement to stay off the market is not due to the patent's scope or strength but simply because the generic has agreed to not compete for a period of time in exchange for valuable financial inducements that the brand-name company gives.

10. This suit concerns GSK's use of such improper tactics (and others) to prevent and/or impede generic competition for Lamictal tablet products ("Lamictal Tablets"), and for Lamictal chewable dispersible tablets ("Lamictal Chewables"), both of which contain the active ingredient lamotrigine. Shortly after GSK launched Lamictal Tablets in or about 1994, the drug quickly became one of GSK's top-grossing products. GSK's sales of Lamictal Tablets in the United States were in excess of $2 billion during the twelve months ending March 2008. GSK's annual domestic sales of the low-dosage strength Lamictal Chewables product were about $50 million in the twelve months preceding the market entry of generic chewables in 2005.[1]

11. Teva, the largest generic pharmaceutical manufacturer in the world, recognized the huge market potential for Lamictal, and in April 2002, was the first generic firm to file ANDAs with the FDA seeking approval to market generic versions of Lamictal Tablets and Lamictal Chewables. Teva's ANDAs contained Paragraph IV certifications that Teva's proposed generics did not infringe any valid or otherwise enforceable patent(s) listed in the Orange Book as covering Lamictal Tablets or Lamictal Chewables, including specifically U.S. Patent No. 4,602,017 ("the '017 patent"). GSK is the assignee of the '017 patent, which claims 3,5-Diamino-6(2,3-dichlorophenyl)-1,2,4-triazine, the active ingredient in Lamictal Tablets and Lamictal Chewables (which is also referred to as "lamotrigine") as well as certain methods of using lamotrigine. The '017 patent had an expiration date of July 22, 2008.

[1] In addition to Lamictal Tablets and Lamictal Chewables (also referred to as "Lamictal CD"), GSK also markets lamotrigine in two other forms: Lamictal ODT (orally disintegrating tablets) and Lamictal XR (extended release). The vast majority of prescriptions are written for Lamictal Tablets. Lamictal Tablets, Chewables, ODT, and XR are not AB-rated to one another.

12. As the first Paragraph IV ANDA filer, Teva stood to receive a significant and potentially highly profitable benefit under 21 U.S.C. 355(j)(5)(B)(iv): 180 days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic Lamictal product. The 180-day exclusivity period could potentially provide Teva with an extremely valuable competitive advantage versus other generics which would enable Teva to have 100% of the generic sales during this 180-day period and charge higher generic prices during this period than in a market with multiple generics. Furthermore, it is well-known in the industry that those generics which are able to take advantage of the 180-day exclusivity periods are able to get a "first mover advantage" resulting in the permanent retention of a larger market share than later entrants, even after other generics enter the market. However, the 180-day exclusivity period does not bar an NDA holder from selling an "authorized generic" or licensing their product to another company to sell an "authorized generic."[2] If a brand company chooses to counter or preempt the initial generic entry with an authorized generic, it could greatly diminish the profit potential of the first ANDA filers' product, which otherwise could have been the sole generic on the market.

13. In August 2002, GSK sued Teva for infringement of the '017 patent based on Teva's Paragraph IV ANDAs seeking approval to market generic versions of Lamictal Tablets and Lamictal Chewables. The filing of these suits triggered an automatic stay of approval of Teva's ANDAs for up to 30 months. The cases were subsequently consolidated (the "Patent Litigation") and eventually proceeded to a five-day bench trial

[2] An authorized generic is simply the brand product sold under generic trade dress at a cheaper price than the brand.

before the Honorable John W. Bissell in January 2005. On the final day of trial, Judge Bissell ruled that Teva "prove[d] by clear and convincing evidence that Claim 1 [of the '017 patent], the alleged invention of lamotrigine, is invalid," and informed the parties that he would deliberate over the course of the next week on the remaining claims, and that a ruling on those claims would be forthcoming.

14. Having already invalidated the claim of the '017 patent that covered the active ingredient of Lamictal, *i.e.*, lamotrigine, it was highly likely that Teva would prevail with respect to the remaining patent claims. These claims were extremely weak in view of Judge Bissell's ruling that claim 1 was invalid. However, both GSK and Teva faced the loss of significant future profits if the court invalidated the '017 patent's remaining claims at issue. GSK stood to lose its patent protection preventing generic competition for Lamictal Tablets and Lamictal Chewables, which would result in a dramatic reduction in GSK's future revenue for both products.

15. Teva also faced a quandary because it knew that its ANDAs for both Lamictal Tablets and Lamictal Chewables were not ready for final approval from the FDA. A final decision in its favor on the '017 patent would have been a Pyrrhic victory for Teva, because it would trigger the running of its 180-day exclusivity period before Teva was ready to profit from its success. Under Hatch-Waxman, Teva's 180-day exclusivity period for generic versions of Lamictal Tablets and Lamictal Chewables would be triggered by the earlier of either: (a) Teva's market entry or (b) a court-entered final decision that the patent(s) subject to the Paragraph IV certification was invalid, unenforceable, and/or not infringed. While Hatch-Waxman creates an opportunity for the first-filer of a Paragraph IV certification (the "first filer") to have up to 180 days of

exclusivity versus other generics, Hatch-Waxman does not guarantee a first filer the right to profit from all (or any) of the 180-day exclusivity period. That is so because, if, for instance, the 180-day period is triggered by a final court decision, but the first filer has not yet obtained final approval from the FDA to market its generic product, the 180-day period may begin and end before the first filer can enjoy any actual sales of its product during that time.

16. Because the FDA had not yet granted Teva approval to market generic versions of Lamictal Tablets or Lamictal Chewables in January 2005, Teva faced the risk that it would *not* be able to reap any of the monetary rewards that come with being the first ANDA filer before the 180-day exclusivity period expired. If Teva's 180-day exclusivity period expired before its generic Lamictal Tablet and Lamictal Chewable products were approved for sale, other competing generic firms with approved AB-rated products might be able to enter the market at the same time as (or even before) Teva. This would mean that not only would Teva not be able to garner the full profits of the 180-day period, but another generic could gain the long-term "first-mover" advantage.

17. Thus, faced with the risk that the court would invalidate the remaining claims of the '017 patent, GSK had an interest in delaying Teva's entry for as long as possible so that GSK could continue to earn monopoly profits on both Lamictal Tablets and Lamictal Chewables. Teva also had an interest in delaying a final court decision finding the '017 patent invalid until it was ready to take advantage of its valuable 180-day period.

18. Recognizing the severe financial risks to both parties, on February 16, 2005, the Defendants entered into a Settlement Agreement and a License and Supply

Agreement ("License Agreement") (jointly, the "Agreements"). Under the Agreements, Teva agreed to not enter the market with a generic version of GSK's $2 billion-a-year Lamictal Tablets product until the July 2008 expiration date of the '017 patent. Thus, even though in January 2005, Teva had already succeeded in invalidating Claim 1 of the '017 patent covering the active ingredient of Lamictal, and even though the remaining claims of the patent at issue were extremely weak and highly likely to be held invalid, the Agreements provided no procompetitive benefit because they delayed Teva's market entry of generic versions of Lamictal Tablets until after the expiration of the '017 patent. As to Lamictal Chewables, GSK granted Teva permission to market a certain quantity of GSK-supplied Lamictal Chewables product beginning June 2005, and an exclusive license to market generic Lamictal Chewables upon receiving final FDA approval for the entire term of the '017 patent including any period of Pediatric Exclusivity GSK would obtain. Also, during the period after the expiration of the '017 patent and any GSK-held regulatory exclusivities that could have prevented Teva from coming to market, GSK agreed not to launch less expensive authorized generics of Lamictal Tablets and Lamictal Chewables in competition with Teva, which was well beyond any powers (exclusionary or otherwise) of the expired '017 patent, and as such constitutes a naked market allocation agreement.

19. The Agreements benefitted GSK by delaying market entry of less-expensive generic versions of Lamictal Tablets until the expiration of the '017 patent, ensuring that Teva would not enter upon final FDA approval of its ANDA in the event that occurred prior to the end of the patent term, and benefitted Teva by ensuring that there would not be a final court decision invalidating the patent before Teva was ready to

use its 180-day exclusivity for generic Lamictal Tablets (along with other benefits discussed below). This would enable Teva to charge higher generic prices during the first 180 days and to maximize its longer-term profits by obtaining the "first mover advantage" noted above. This also benefitted GSK because the higher prices Teva would charge during the first 180 days meant that there would be less competitive pressure on GSK to reduce prices during this period, such that it would lose less market share during this period than if there were multiple generics in the market. GSK also benefitted in a broader sense in that the Agreements as a whole delayed not only the entry of Teva's generic Lamictal Tablet products, but other generics as well because without a court ruling holding the patent invalid or not infringed, no other generic could enter until Teva exercised its 180-day exclusivity period. Thus, by and through these Agreements, Teva and GSK afforded themselves a guarantee of higher revenues during these periods of time which resulted in anticompetitive overcharges being thrust upon purchasers.

20. In exchange for its agreement to delay entry of its generic Lamictal Tablets, Teva received substantial financial inducements that went beyond what Teva could have achieved if it was fully successful in the patent litigation. GSK and Teva have expressly stated that the inducements discussed below were part of the "consideration" that GSK offered Teva "in reaching agreement to settle."

21. First, Teva was permitted to sell limited amounts of a generic version of the Lamictal Chewable product, starting on June 1, 2005. In pleadings from a subsequent litigation between the Defendants, GSK acknowledged that permitting Teva to market a generic version of the Lamictal Chewable product beginning in June 2005 was a benefit given to Teva in exchange for Teva's agreement to delay marketing of its generic version

of the far more lucrative Lamictal Tablets product until the expiration date of the '017 patent in July 2008. In effect, even though claim 1 of the '017 patent was held invalid and Teva was very likely to prevail as to the remaining asserted claims, Teva agreed not to market a competing generic for the entire patent term. As indicated below, any Pediatric Exclusivity GSK obtained could not further delay Teva's generic entry unless there was a ruling by Judge Bissell that the '017 patent was valid and infringed by Teva's proposed generics.[3]

22. Significantly, even though both the Lamictal Tablet and Lamictal Chewable products were subject to the same patent claims (and Teva's chances of litigation success were the same for both products) Teva and GSK agreed that Teva would enter the market for the less profitable Lamictal Chewable product three months after the settlement, but that Teva would wait the entire patent term – which amounted to three or more years -- to launch a generic version of the exponentially more profitable Lamictal Tablet product. The disparate treatment and entry dates that GSK and Teva negotiated for the two products (both of which were subject to the exact same patent claims and litigation risks) reflects the fact that the parties did not choose (or even attempt to choose) entry dates for the two products that reasonably reflected the probability that the asserted claims of the '017 patent were invalid. Rather, the disparate entry dates reflect the reality that Teva was given financial inducements to delay entry of its generic Lamictal Tablet product. While the negotiated deal benefitted Teva and GSK,

[3] Pediatric Exclusivity attaches on an ANDA-by-ANDA basis. *See* paragraph 49 below. Thus, even though Pediatric Exclusivity would not delay entry of Teva's proposed generics, that exclusivity (depending on the circumstances) could delay final approval of other generic manufacturers' ANDAs.

the deal was not structured with any concern or interest for purchasers or consumers who need treatment for epilepsy, bipolar disorder, and other medical conditions at lower prices. The purchaser/consumer benefits gained by the entry of Teva's generic Lamictal Chewable in June 2005 pale in comparison to the purchaser/consumer harm incurred by the anticompetitive three-year delay in the entry of Teva's less-expensive generic version of Lamictal Tablets.

23. Upon information and belief, Teva sought (and GSK gave) a second inducement to Teva to delay its entry of generic Lamictal Tablets: that GSK agreed to refrain from launching its own competing authorized generic versions of Lamictal Tablets and Lamictal Chewables until January 2009 (*i.e.*, 180 days after Teva was on the market with a generic version of Lamictal Tablets, and over three years after Teva was on the market with a generic version of Lamictal Chewables). This inducement was unquestionably beyond the exclusionary scope of the patent because Teva and GSK agreed not to compete with respect to generic products during a period when: (a) the '017 patent had expired and there were no GSK-held regulatory exclusivities that could bar Teva from coming to market; and (b) there were no patents or regulatory exclusivities that would bar GSK from launching an authorized generic product. Nothing in Hatch-Waxman would allow Teva's first-filer exclusivity to bar GSK from launching its own authorized generic versions of Lamictal Tablets and Lamictal Chewables during Teva's exclusivity periods. Furthermore, because Teva filed and maintained a Paragraph IV certification, any Pediatric Exclusivity that GSK later obtained could not delay Teva's ability to market Lamictal Tablets or Chewables after the expiration of the '017 patent term. As alleged below, but for the Agreements, GSK had an incentive to launch its own

authorized generic versions of tablets and chewables, and has a history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics.

24. A 2012 FDA list of authorized generics shows that between January 1, 1999 and January 9, 2012, GSK launched authorized generics when faced with generic competition to at least ten of its branded pharmaceuticals products, including: Augmentin and Cutivate in 2003; Amoxil, Paxil, and Wellbutrin SR in 2004; Retrovir in 2005; Flonase and Zantac in 2006; Imitrex in 2007; and Paxil CR in 2010. Available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605.pdf.

25. The Federal Trade Commission ("FTC") and other government entities have recognized that the presence of an authorized generic significantly benefits purchasers by both increasing purchaser choices and also creating price competition which reduces generic prices during the 180-day period. By agreeing to not exercise its lawful right to launch authorized generics until January 2009, GSK was illegally agreeing to restrain or limit its ability to compete during this period.

26. As to Lamictal Tablets, absent the anticompetitive inducements that GSK gave to Teva to delay Teva's launch of its generic version of Lamictal Tablets, Teva would have pressed for (and the parties would have agreed to) a settlement allowing Teva to come to market with its generic Lamictal Tablets earlier than the Agreements allowed. Alternatively, without the provision wherein GSK agreed not to launch authorized generics in competition with Teva until January 2009, the parties would have entered an agreement that provided for entry of Teva's generic version of Lamictal Tablets earlier than the Agreements allowed. As alleged in more detail below, Teva has admitted that

the agreement that GSK would not launch its own authorized generic was "critical here because the benefit conferred to Teva from this Settlement was of such a short duration." Further, assuming there would have been no settlement between the Defendants, the parties would have continued to litigate and either: (1) Teva would have prevailed allowing for an even earlier launch of generic versions of Lamictal Tablets as well as triggering Teva's 180-day marketing exclusivity, or (2) Teva would have launched its generic version of Lamictal Tablets "at risk" during the course of the patent litigation after expiration of the 30-month stay and after Teva received final approval from FDA. In sum, "but for" the anticompetitive Agreements between the Defendants, generic competition in the market for Lamictal Tablets would have occurred sooner and would have resulted in substantial savings to the Plaintiffs.

27. As to Lamictal Chewables, absent the Agreements, GSK would have launched an authorized generic in competition with Teva's generic Lamictal Chewable product, and but for GSK's agreement not to compete, price competition between Teva's generic Lamictal Chewables product and GSK's own authorized generic Lamictal Chewables product would have resulted in lower prices for Lamictal Chewables to the Plaintiffs.

28. The Agreements caused illegal anticompetitive harm to the direct purchasers of Lamictal Tablets and/or Teva's generic version of Lamictal Tablet by causing them to pay higher, artificially-inflated prices for those products than they otherwise would have absent the conduct alleged herein. Plaintiffs, and all others similarly situated, were injured and sustained damages in the form of overcharges for branded and generic forms of Lamictal Tablets as a direct result of GSK and Teva's

unlawful Agreements that accompanied the settlement of the '017 patent litigation. This civil antitrust case seeks overcharges (trebled) paid by Plaintiffs and a class of all other persons or entities in the United States and its territories who purchased Lamictal Tablets directly from GSK and/or generic lamotrigine tablets directly from Teva at any time during the Class Period of from at least February 17, 2008 until the effects of Defendants' conduct cease.

29. In addition, the Agreements caused illegal anticompetitive harm to the direct purchasers of Lamictal Chewables and/or Teva's generic version of Lamictal Chewables by causing them to pay higher, artificially-inflated prices for those products than they otherwise would have absent the conduct alleged herein. Plaintiffs, and all others similarly situated, were injured and sustained damages in the form of overcharges for branded and generic forms of Lamictal Chewables as a direct result of GSK and Teva's unlawful Agreements that accompanied the settlement of the '017 patent litigation. This civil antitrust case seeks overcharges (trebled) paid by Plaintiffs and a class of all other persons or entities in the United States and its territories who purchased Lamictal Chewables directly from GSK and/or generic lamotrigine chewables directly from Teva at any time during the Class Period of from at least February 17, 2008 until the effects of Defendants' conduct cease.

II. JURISDICTION AND VENUE

30. This Consolidated Amended Class Action Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and the costs of suit, including a reasonable attorneys' fee, for the

injuries sustained by Plaintiffs and members of the Class resulting from violations by Defendants, as hereinafter alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

31. The Defendants named herein are found or transact business within this judicial district, and the interstate trade and commerce hereinafter described is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

32. Plaintiff LWD is a corporation organized under the laws of the State of Louisiana and maintains its principal place of business at 2085 I-49 South Service Road, Sunset, Louisiana 70584. LWD purchased branded and generic Lamictal Tablets and Lamictal Chewables directly from GSK and Teva during the Class Period as defined below, and was injured by the illegal conduct described herein.

33. Plaintiff King Drug, a corporation organized under the laws of the State of South Carolina, which maintains its principal place of business at 605 W. Lucas Street, Florence, South Carolina 29501, purchased branded and generic Lamictal Tablets and Lamictal Chewables directly from GSK and Teva during the Class Period as defined below, and was injured by the illegal conduct described herein.

33. On information and belief, Defendant SmithKline Beecham Corporation is a public corporation organized and existing under the laws of the Commonwealth of Pennsylvania and having a registered office at One Franklin Plaza, Philadelphia,

Pennsylvania 19102. SmithKline Beecham Corporation operates under the business name GlaxoSmithKline. GSK is in the business of, among other things, developing, manufacturing, distributing, advertising, and selling branded Lamictal Tablets and Lamictal Chewables products throughout the United States.

34. Defendant Teva Ltd. is a corporation organized and existing under the laws of the State of Israel and having registered office at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Teva Ltd. is the ultimate parent company of Teva USA.

35. Defendant Teva USA is incorporated under the laws of the State of Delaware, with its principal place of business in North Wales, Pennsylvania. Teva USA develops, manufactures, and sells generic products in the United States. Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.

36. Teva Ltd. manufactures the generic lamotrigine tablet product that Teva USA began selling in the United States in July 2008, and has sold generic lamotrigine chewables in the United States beginning in June 2005.

IV. CLASS ACTION ALLEGATIONS

37. Plaintiffs bring this action on behalf of themselves and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a class defined as follows:

> All persons or entities in the United States and its territories who purchased Lamictal Tablets directly from GSK, or who purchased a generic version of lamotrigine tablets directly from Teva, at any time during the Class Period from at least February 17, 2008 until the effects of Defendants' conduct ceases (the "Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

Additionally, Plaintiffs bring this action on behalf of themselves and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a class defined as follows:

> All persons or entities in the United States and its territories who purchased Lamictal Chewables directly from GSK, or who purchased a generic version of lamotrigine chewables directly from Teva, at any time during the Class Period from at least February 17, 2008 until the effects of Defendants' conduct ceases (the "Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities

38. Members of the Class are so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiffs, it is believed to be between approximately fifty and one-hundred fifty. Furthermore, the Class is readily identifiable from information and records in the possession of Defendants.

39. Plaintiffs' claims are typical of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by the Defendants, *i.e.*, they paid artificially inflated prices for Lamictal Tablets and/or Lamictal Chewables and were deprived of the benefits of competition from less-expensive generic versions of Lamictal Tablets and/or Lamcital Chewables as a result of Defendants' anticompetitive conduct.

40. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

41. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, particularly class action antitrust litigation in the pharmaceutical industry.

42. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because the Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

43. Questions of law and fact common to the Class include:

a. whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. whether a relevant market needs to be defined in this case in light of the existence of direct evidence of GSK's power to exclude generic competition and charge supra-competitive prices for Lamictal Tablets;

c. if a relevant market needs to be defined, the definition of the relevant market for analyzing GSK's monopoly power, and whether GSK had monopoly power in the relevant market;

d. whether Defendants' actions illegally maintained Defendants' monopoly power in the relevant market;

e. whether Defendants' actions constituted an illegal market allocation agreement;

f. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

g. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of its direct purchaser customers and if so, the appropriate measure of damages.

44. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that may not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

45. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTUAL ALLEGATIONS

A. The Defendants' Products and the Nature of Sales of Generic Equivalent Products

46. GSK sells Lamictal Tablets in strengths of 25 mg, 100 mg, 150 mg, and 200 mg pursuant to New Drug Application No. 20-241, which was approved by the FDA in 1994. GSK sells Lamictal Chewables in strengths of 2 mg, 5 mg and 25 mg pursuant to New Drug Application No. 20-764, which was approved by the FDA in August 1998. For the twelve months ending March 2008, GSK's sales of Lamictal Tablets in the United States exceeded $2 billion, according to IMS data. The low-dosage strength Lamictal Chewable products had annual domestic sales of about $50 million in the twelve months preceding the market entry of generic chewables in 2005.

47. Upon receiving FDA approval of its NDA for Lamictal Tablets on December 27, 1994, GSK was awarded a five-year new chemical entity ("NCE") exclusivity, which expired on or about December 27, 1999. During this five-year period, the FDA could not grant final approval to any ANDA, meaning GSK's Lamictal Tablets would be free from generic competition for at least a five-year period. Subsequently, GSK received approval for a new label indication for the adjunctive treatment of Lennox-Gastaut syndrome in pediatric and adult populations. As part of that approval, Lamictal Tablets were awarded a seven-year orphan drug exclusivity ("ODE"), commencing on August 24, 1998. Congress enacted the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1982), in order to encourage firms to develop pharmaceuticals to treat rare diseases and conditions. The Orphan Drug Act establishes a seven-year ODE period during which no ANDA for the same use of a generic version of the drug can be approved. 21 U.S.C. § 360cc. However, ODE is indication-specific, meaning that the FDA can approve an ANDA for non-ODE protected uses during the seven-year period. The ODE for Lamictal Tablets expired on or about August 24, 2005, although since Lamictal Tablets were approved for other non-ODE protected indications, ANDAs could be approved for the non-ODE protected indications prior to August 24, 2005.

48. GSK received FDA approval of its NDA for Lamictal Chewables in August 1998, and received a three-year marketing exclusivity for this drug. During this three-year period, generic versions of this drug could not receive ANDA approval. ODE also applied to Lamictal Chewables, but was subject to the same restrictions as concerns Lamictal Tablets noted above.

49. The '017 patent, which expired on July 22, 2008, was (and has been) the only patent listed in the Orange Book for Lamictal Tablets. The '017 patent, along with another patent (U.S. Patent No. 5,698,226), were listed in the Orange Book as pertaining to Lamictal Chewables, although as alleged below, this second patent played no role in the Patent Litigation between GSK and Teva. In addition, in 2007 (well after execution of the Agreements between GSK and Teva at issue here) GSK received a 6-month Pediatric Exclusivity, which is a regulatory exclusivity that prevents the FDA from approving the generic product until six months after (1) the expiration of the last-expiring valid, infringed, and enforceable patent listed in the Orange Book, or (2) regulatory exclusivity in existence at the time of the granting of the Pediatric Exclusivity, whichever is later. The application of Pediatric Exclusivity is determined on an ANDA-by-ANDA basis in the following respects: (a) Pediatric Exclusivity will not attach to the end of a patent as concerns any ANDA that contains a Paragraph IV certification to the patent; and (b) Pediatric Exclusivity will not attach to the end of a patent as concerns any ANDA that has been found not to infringe the patent. Here, with the granting of Pediatric Exclusivity, the total exclusivity for Lamictal Tablets ended in January 22, 2009, but only as concerns those ANDAs that (unlike Teva's) did not contain Paragraph IV certifications to the '017 patent. As to Teva's ANDA for Lamictal Tablets, the Pediatric Exclusivity was not a bar to the FDA granting final approval on August 30, 2006 (see below), even though the '017 patent expired in July 2008.

50. On or about April 1, 2002, Teva filed ANDA No. 76-388, seeking approval to manufacture and sell a generic version of Lamictal Tablets. A short time later, Teva filed ANDA No. 76-420, seeking approval to manufacture and sell a generic

version of Lamictal Chewables. Teva's ANDAs were accompanied by Paragraph IV certifications which stated that every claim, except claim 5, of the '017 patent was invalid, unenforceable, and/or not infringed by Teva's proposed generic lamotrigine products. Claim 5, which purported to cover an injectable solution containing lamotrigine, was not at issue since Teva was not seeking FDA approval to sell an injectable version of lamotrigine. Teva also filed a Paragraph IV certification to the second patent listed in the Orange Book regarding Lamictal Chewables. Since Teva was the first generic firm to file substantially complete ANDAs for AB-rated generic equivalents to Lamictal Tablets and Lamictal Chewables with Paragraph IV certifications to the '017 patent, Teva was entitled to separate 180-day exclusivities for generic versions of Lamictal Tablets and Lamictal Chewables, during which time no other generic manufacturers could sell generic versions of Lamictal Tablets or Lamictal Chewables pursuant to an ANDA (although GSK had the legal right to sell authorized generic versions of the products through its NDAs).

51. The FDA ultimately approved Teva's ANDA for lamotrigine chewables on June 21, 2006 and Teva's ANDA application for lamotrigine tablets on August 30, 2006. In so doing, the FDA found that: (a) Teva's lamotrigine chewables are bioequivalent to GSK's Lamictal Chewables – *i.e.*, that Teva's lamotrigine chewables have the same safety and efficacy as, and are AB-rated to GSK's Lamictal Chewables of the same dosage strengths; and (b) Teva's lamotrigine tablets have the same safety and efficacy as, and are AB-rated to GSK's Lamictal Tablets of the same dosage strengths.

52. On information and belief, in addition to Teva, at least four other companies filed ANDAs to sell generic Lamictal Tablets by the time Defendants entered

into the Agreements in February 2005. On information and belief, by February 2008, that number had increased to at least twenty-two.

53. Further, on information and belief, by February 2008, at least 9 ANDAs for generic Lamictal Tablets (other than Teva's) received tentative approval.[4] Two of them received tentative approval in June 2006, even before Teva's product was approved. Consequently, had Teva launched its Lamictal Tablets by August of 2006, there would have been numerous generic Lamictal Tablet products on the market by February 2008.

B. The Patent Litigation and Settlement.

54. Soon after filing its ANDAs and Paragraph IV certifications, Teva sent GSK notifications of the Paragraph IV certifications as required by the regulations. Within 45 days of receiving Teva's Paragraph IV certifications to the '017 patent, GSK filed Civil Action No. 02-3779 and Civil Action No. 02-4537 against Teva in federal court in New Jersey in 2002, alleging that Teva's two ANDAs infringed the '017 Patent. The two patent lawsuits were consolidated in November 2002. Both suits were filed within 45 days of receipt of the Paragraph IV notices from Teva, entitling GSK to automatic 30-month stays of approval of both of Teva's ANDAs. GSK did not sue Teva with respect to the second patent listed for Lamictal Chewables.

55. Following discovery, the Patent Litigation proceeded to a bench trial before Judge Bissell from January 18 to January 27, 2005. By this time, the 30-month stays of regulatory approval on both of Teva's ANDAs had either expired or were about

[4] Tentative approval is granted to ANDAs that have satisfied FDA's safety and efficacy requirements, but are not eligible for final approval due to the existence of patent or regulatory exclusivities held by other companies, such as the 30 month stay held by GSK or the 180-day period held by Teva.

to expire, *i.e.*, the stay on Teva's tablet ANDA expired on December 26, 2004, while the stay on Teva's chewable ANDA was set to expire on February 16, 2005. Teva, however, still had not received final approval for either of its Lamictal ANDAs due ostensibly to outstanding safety and efficacy issues that had yet to be resolved to the FDA's satisfaction.

56. On the final day of trial, Judge Bissell ruled from the bench that Teva succeeded in establishing—by clear and convincing evidence—that claim 1 of the '017 patent, which claimed the chemical compound 3,5-diamino-6-(2,3-dichlorophenyl)-l,2,4-triazine, was invalid as anticipated by the prior art.

57. In light of Judge Bissell's invalidity ruling, Teva was highly likely to succeed in invalidating the remaining asserted claims of the '017 patent, which included claims 3, 4 and 6-12, based on its obviousness-type double patenting theory. That is, Judge Bissell's ruling that the chemical compound recited in claim 1 was anticipated by the prior art, severely weakened GSK's validity positions with respect to the remaining asserted claims, as explained further below.

58. Before Judge Bissell, Teva argued that each of the remaining asserted claims were invalid because of GSK's "double patenting" of the claimed subject matter. Obviousness-type double patenting prohibits a party (such as GSK) from obtaining an improper extension of its patent rights by obtaining claims in a later patent that are not patentably distinct from claims in an earlier patent. In essence, Teva's obviousness-type double patenting theory alleged that the remaining asserted claims of the '017 patent were not patentably distinct from another GSK-owned patent that issued four years before the '017 patent. The earlier GSK patent, U.S. Patent No. 4,311,701 ("the Roth

patent"), similarly claimed, *inter alia*, "[a] method of treatment of convulsions" using a related chemical compound (*i.e.*, 3,5-diamino-6-(2-chlorophenyl)-1,2,4-triazine). The Roth patent, however, expired on August 16, 1999, many years before the expiration of the '017 patent. The remaining asserted claims of the '017 patent could not be considered patentably distinct from the claims of the earlier Roth patent, if the remaining asserted claims were determined to be obvious in view of the Roth claims. Each of the remaining asserted claims of the '017 patent recited a method of treating convulsions or epilepsy using the *chemical compound recited in claim 1*, or recited "an effective anticonvulsant amount" of the *chemical compound recited in claim 1*. After the Court ruled that claim 1 of the '017 patent was invalid as anticipated (and accordingly, the chemical compound 3,5-diamino-6-(2,3-dichlorophenyl)-l,2,4-triazine was in the prior art), then it was highly likely that the remaining asserted claims would have been obvious in view of the Roth claims.

59. Prior to the Court's ruling, both GSK and Teva recognized the significant impact a ruling that claim 1 was anticipated would have on the validity (or lack thereof) of the remaining asserted claims. In fact, during closing arguments, GSK itself told the Court that Teva's "double patenting defense is premised on the fact that it wins on anticipation of Claim 1," a position which GSK described as "Teva's position pretrial." GSK further acknowledged that Teva's double patenting defense as to the remaining asserted claims required that "Teva passed the first hurdle on anticipation." Once that first hurdle on anticipation was surmounted by the Court's ruling, GSK and Teva should have known that an invalidity ruling as to each of the remaining asserted claims was highly likely.

60. On the final day of trial, Judge Bissell also indicated that he would endeavor "in the course of the next week" to reach a determination on the validity of the remaining asserted claims. An imminent ruling on the remaining asserted claims raised concerns for both parties: (1) for Teva, that a final court decision could lead to the triggering of its 180-day exclusivity period for its generic version of Lamictal Tablets and Lamictal Chewables before Teva had received final FDA approval; and (2) for GSK, that generic entry may be imminent for Lamictal Tablets and Lamictal Chewables.

(1) A Court Decision Would Dramatically Affect the Market Conditions

61. Assuming, as the parties must have in light of the Court's invalidation of claim 1, it was highly likely that Teva would prevail in demonstrating the asserted claims of the '017 patent were invalid, then Teva would have been permitted to start selling its products immediately upon FDA approval, which was ultimately granted in 2006. Notably, because Teva was sued under the same patent claims and patent infringement theories for its generic versions of both Lamictal Tablets and Lamictal Chewables, its chances of invalidating the asserted claims were the same for its generic versions of both products.

62. Moreover, the successful invalidation of the asserted claims of the '017 patent would dramatically change the competitive landscape for both GSK and Teva. Under the applicable statutory regime, Teva's 180-day exclusivity period would begin to run from the earlier of either: (1) Teva's first commercial marketing of either generic product (although a launch of generic Lamictal Tablets would not trigger the 180-day period on generic Lamictal Chewables, and vice versa); or (2) a final court decision holding the '017 patent invalid, unenforceable, or not infringed regardless of whether

Teva had commenced sales. Thus, the entry of a final court decision invalidating the asserted claims of the '017 patent would start the clock on Teva's 180-day exclusivity period for that patent even if Teva did not have FDA-approval to sell the product(s).

63. Moreover, the invalidation of the asserted claims of the '017 patent would open the floodgates of competition for Lamictal Tablets and Lamictal Chewables because within six months after such final decision invalidating the asserted claims other generics would be permitted to start selling their AB-rated generic products upon receiving FDA final approval. Also, if the asserted claims of the '017 patent were invalid, Pediatric Exclusivity would not apply to prevent FDA approval of all ANDA applications by other generic manufacturers of either Lamictal Tablets or Chewables. The Pediatric Exclusivity does not attach to the end of any patent that has been found to be invalid or unenforceable, and it does not apply to any ANDA applications that are accompanied by a Paragraph IV certification that the patent is invalid or not infringed by the proposed ANDA product unless and until there is a court decision which affirmatively holds that the patent is both valid and infringed by the ANDA product at issue.

64. In the alternative, even if there was no final decision in the Patent Litigation by August 2006 (when Teva had received final approval on both of its ANDAs, and after the 30-month approval stay had expired), then Teva could have entered the market "at-risk" for both tablets and chewables, thus triggering the start of its 180-day periods and allowing any other approved ANDA filers to come to market six months later.

65. It is well known in the industry that Teva is the most prolific launcher of generic versions of brand-name drugs "at-risk," that launching at-risk is a core part of its

business strategy, that Teva possesses insurance covering portions of this risk, and that as a multibillion-dollar-a-year company Teva possesses the financial wherewithal above and beyond "at-risk" insurance to cover potentially non-insured losses stemming from at-risk launches. It is also well known that most "at-risk" launches, or threats of them, generally give rise to settlements of the associated patent litigation that allow the less expensive generic product to remain on the market. Here, Teva would have been motivated to launch "at-risk" because, after successfully invalidating claim 1 of the '017 patent, it would have had a high level of confidence that it would win the patent suit.

(2) <u>It Would Be to Teva and GSK's Financial Disadvantage If The Court Invalidated The Patent.</u>

66. The invalidation of all of the asserted '017 patent claims posed risks to both GSK and Teva. GSK faced the danger that if the court invalidated the other patent claims (which was highly likely), there would be a dramatic reduction in future revenue due to the loss of patent exclusivity of Lamictal Tablets and Lamictal Chewables. The highly likely probability that Teva might win the trial also placed Teva in a quandary because a successful final court decision would trigger the beginning of Teva's 180-day exclusivity period for its generic Lamictal Tablets and Lamictal Chewables prior to receiving FDA approval, which meant that Teva would lose some (if not all) of its valuable exclusivity. As alleged above, Teva's ANDA application for generic lamotrigine chewables did not receive final approval until June 21, 2006 and its ANDA application for generic lamotrigine tablets did not receive Final Approval until August 30, 2006. Accordingly, if the January 2005 bench trial resulted in a final court decision before December 2005, then Teva's 180-day exclusivity would be triggered by a court decision and expire for both generic Lamictal Tablets and generic Lamictal Chewables

before Teva could even bring those products to market. Any other competing generic that had final approval of their ANDAs for generic versions of Lamictal Tablets or Lamictal Chewables as of June 2006 (after Teva's exclusivity period had expired) could enter the market before (or at the same time) as Teva. As alleged above, when the Defendants entered into their illegal agreement, four other companies had already filed ANDAs to sell generic Lamictal Tablets, and over the next two years 20 more generics filed ANDAs. Moreover, at least one generic rival received tentative approval in June 2006 for its generic Lamictal Tablets, even before Teva's product was approved. So, Teva faced the risk that if its 180-day exclusivity ended before its product was approved another rivals' product might enter the market before Teva's, thereby gaining not only the significant profits during that period but also the long-term "first-mover" advantage.

67. Thus, GSK had an interest in delaying Teva's entry for as long as possible so that GSK could continue to earn monopoly profits on both Lamictal Tablets and Lamictal Chewables, and Teva had an interest delaying a final court decision until it would be in a position to take advantage of its valuable 180-day exclusivity for generic Lamictal Tablets and Lamictal Chewables.

68. Recognizing the risks to both parties (*i.e.*, that it was highly likely that GSK would lose its patent protection entirely and that Teva might not be permitted to take full advantage of its success), the parties immediately started settlement negotiations, and on February 2, 2005, the parties had a conference with the Court during which they asked the Court to refrain from ruling on the validity of the remaining claims.

69. Two weeks following that conference, GSK and Teva reached a settlement, the terms of which are set forth in the Agreements. The Settlement

Agreement expressly provides that the inducements set forth in the Agreements are part of the "consideration" that GSK offered Teva "in reaching agreement to settle."

70. The settlement permitted Teva to sell limited amounts of generic lamotrigine chewables in the U.S., by no later than June 1, 2005 – approximately 37 months prior to the expiration of the '017 patent. Even though Teva's ANDA to sell its generic version of Lamictal Chewables did not receive final approval from the FDA until June 2006, GSK supplied Teva with chewable lamotrigine product, which Teva began selling as an authorized generic on May 25, 2005.

71. Under the Agreements, GSK additionally granted Teva: (a) a royalty-free, non-transferable license under the '017 patent to import, manufacture, have manufactured and have sold Teva's generic version of Lamictal Tablets in the United States[5], starting on July 21, 2008, at 5:00 p.m. Pacific time, which was when the '017 patent expired; and (b) a waiver of any potential Pediatric Exclusivity applicable to Teva's generic version of Lamictal Tablets. Even if GSK ultimately received Pediatric Exclusivity, it would have little or no value – such exclusivity would not apply against Teva unless Judge Bissell found the '017 patent valid and infringed by Teva's ANDA products prior to Teva entering the market (which it could have done at risk upon receiving final FDA approval). Thus Pediatric Exclusivity as to Teva's ANDA was at best a conditional, theoretical right which could not ripen, because at the time of the Agreements, the court did not enter a judgment finding the '017 patent valid and infringed. In fact, at the time of the Agreements, no Pediatric Exclusivity had been granted to GSK by the FDA (it was received in 2007 after the FDA finally approved Teva's generic Lamictal Tablet, and

[5] Includes Puerto Rico.

after Teva's generic Lamictal Tablet could have been on the market "at risk" but for the Agreements – and it could not have applied to Teva). Thus, even though Teva had already succeeded in invalidating the claim covering the chemical compound lamotrigine, which is the active ingredient of Lamictal, and even though it was highly likely that the Court would invalidate the patent's other asserted claims, the settlement had no procompetitive benefit because it gave little or no discount or reduction to the patent's exclusionary power (*i.e.*, Teva agreed to settle without gaining any right to enter with its generic version of Lamictal Tablets prior to the patent's expiration).

72. Furthermore, even though Teva's generic versions of both Lamictal Tablets and Lamictal Chewables were subject to the same patent claims (and thus, Teva's chances of litigation success were the same for both products), Teva was allowed to start selling a generic version of the significantly smaller product within three months after the settlement, while it agreed to wait at least three years (until the expiration of the patent term) to start selling a generic version of the more than $2 billion a year product. The significantly different entry dates reflect the fact that the parties did not structure the settlement to reasonably reflect the probability that Teva would successfully invalidate all asserted claims of the patent. Rather, it reflects the reality that Teva was given financial inducements to delay entry of its generic Lamictal Tablet product.

73. Because Teva's generic versions of Lamictal Chewables were AB-rated only to the low-dosage strength branded Lamictal Chewables and were not AB-rated to Lamictal Tablets, the generic versions Lamictal Chewables that Teva sold could not be substituted for branded Lamictal Tablets, and thus prior to July 2008 Teva could not provide lower-priced generic substitutes for Lamictal Tablets that would: (a) be broadly

substituted for the higher-priced Lamictal Tablets, or (b) otherwise efficiently compete with branded Lamictal Tablets. Furthermore, the agreement to delay Teva's generic version of Lamictal Tablets from entering the market until after the close of business on July 21, 2008 and GSK's agreement to refrain from launching its own authorized generic Lamictal Tablet until January 2009 had no procompetitive benefit because GSK was conferring rights under the Agreements which were beyond the exclusionary scope of the '017 patent, which expired in July 2008.

74. Teva received significant consideration, incentives, and benefits in exchange for its agreement to delay generic entry by: (a) abandoning its efforts to invalidate the asserted claims of the '017 patent; and (b) not competing against GSK's Lamictal Tablets with a less-expensive generic version until the '017 patent expired. First, Teva was permitted to enter the U.S. market within a few months with an authorized generic version of the much smaller Lamictal Chewables product. In pleadings from a subsequent Teva-GSK litigation, GSK acknowledged that its agreement allowing Teva to enter in three months with a generic version of the smaller Lamictal Chewable product "formed part of the bargain between GSK and Teva" and was one of the "benefits" that Teva received for agreeing to abandon its efforts to invalidate the '017 patent.

75. Second, because Teva was not ready to take advantage of its 180-day marketing exclusivity in January 2005, the agreement to delay entry virtually guaranteed Teva the right to use all or most of its 180-day exclusivity periods for Lamictal Tablets. GSK also benefitted because the Agreements delayed not only the entry of Teva but other generics as well. Thus, by and through these Agreements, Teva and GSK afforded

themselves a mutually beneficial guarantee of higher revenues at the expense of their customers.

76. In addition to the above incentives provided to Teva for its agreement to delay launch of a Lamictal Tablet generic, GSK further agreed to not to launch an authorized generic until January 2009, (*i.e.*, 180 days after Teva was on the market with Lamictal Tablets, and over three years after Teva was on the market with Lamictal Chewables). This constituted a naked agreement not to compete, which extended beyond the exclusionary scope of the patent, which was due to expire in July 2008. At the time these Agreements were drafted, a pharmaceutical company such as GSK that marketed a brand-name drug under an NDA would often introduce – either by itself or through an affiliate – an authorized generic at the same time or just before generic entry was anticipated. As of 2005, GSK had a history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. *See supra* at paragraph 24.

77. A brand company's launch of an authorized generic is extremely damaging to any first-filer generic, such as Teva, because it results in lost market share (*i.e.*, fewer units sold), reduced profits because price competition between the generic and authorized generic forces down prices, and a reduction in the generic's long-term "first mover advantage." As the FTC noted in a June 2009 report on Authorized Generics, "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [Authorized Generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [Authorized Generic]."

78. Notably, while a brand company can lower the prices on its brand products instead of launching an authorized generic (which was an option left open to GSK under the Settlement), that option does not present the same danger to a generic such as Teva, and does not result in the same savings to purchasers. This is because many states have regulations that either require or strongly encourage pharmacists to automatically fill prescriptions with only an AB-rated generic version of a drug in most situations. Thus, even if an NDA holder (such as GSK) lowers the price of its brand drug, state regulations are a barrier that prevent or impede the branded drug from being used for most prescriptions. The result is that most of a generic's sales volume is unaffected by a reduction in the brand price and the generic does not feel the competitive pressure to lower its prices in response to a drop in the branded price (in contrast to the situation where a branded company launches an authorized generic). Thus, while an NDA holder can try to compete against a generic drug through various means other than launching an authorized generic, those competitive options are far weaker and do not provide nearly the consumer savings and benefits as the launch of a true authorized generic. Consequently, GSK's agreement to restrict its competitive responses to far less effective, secondary options was an illegal, anticompetitive agreement by which the parties agreed to restrict until January 2009 competition that would undermine Teva's prices, and consequently resulted in overcharges to purchasers.

79. Indeed, in its June 2009 report regarding Authorized Generics, the FTC expressly concluded that a generic manufacturer might agree to delay the sale of its generic product in exchange for a brand company's agreement (such as the one involved here) to not launch an authorized generic to consumers' detriment:

> To prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand's agreement not to launch an authorized generic – that is, a brand's agreement not to compete with the generic through an AG – during the generic's 180 days of marketing exclusivity…Such agreements can harm consumers …

80. According to Teva's pleadings in a 2008 litigation regarding these products, during the settlement negotiations GSK and Teva specifically considered the possibility that GSK might want to sell an authorized generic during Teva's six-month exclusivity periods, but the parties agreed that GSK would not be permitted to do so. According to Teva, GSK's agreement to not launch an authorized generic until January 2009 was a critical and central consideration for Teva's acceptance of the settlement and delayed entry dates for generic Lamictal Tablets. For example, Teva stated in the 2008 litigation, that GSK's agreement to not compete against Teva by selling an authorized generic during the first 180 days in which Teva was selling generic Lamictal Tablets was:

> **[A]n important component of the settlement between the parties and formed part of the <u>inducement to Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation</u>**.
>
> * * *
>
> …the **<u>key consideration</u>** Teva bargained for in [the License and Supply Agreement].
>
> (Emphasis added).

81. GSK's agreement to not launch its own authorized generic Lamictal product(s) before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic Lamictal Tablets. GSK believed it would be profitable to launch its own authorized generic Lamictal product(s),

as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal product(s) before January 2009 and it would not have done so.

82. Thus, according to Teva, GSK's agreement to not launch an authorized generic was a "key" and "important" consideration of Teva's decision to relinquish its attacks on the '017 patent's validity. Indeed, Teva received more from the settlement than it would have received if it had won the patent litigation. That is, Teva extracted a market allocation agreement that entitled it to the entire generic market for Lamictal Tablets for its 180-day exclusivity period and restrained competition in the generic market for Lamictal Chewables.

83. Absent GSK's illegal agreement to refrain from competing against Teva by selling an authorized generic prior to January 2009 (and absent the valuable financial inducements alleged above), Teva would have sought an entry date for its generic version of Lamictal Tablets earlier than the entry date it accepted in the Settlement. As Teva acknowledged in its pleadings in the subsequent litigation, Teva believed that GSK's agreement to not launch an authorized generic was critical because Teva was only getting a short period of time to sell its generic Lamictal Tablet product before other generics were free to enter the market. As Teva stated, GSK's agreement to refrain from competing against Teva by selling an authorized generic prior to January 2009 was:

> **critical here, because the benefit conferred to Teva from this License Agreement was of such a <u>short duration</u>**. GSK's pediatric exclusivity under its patent was to expire on January 22, 2009. . . . Thus, **the benefit**

> **to Teva of the License Agreement was a brief, six-month window in which it would be the first and only supplier of generic lamotrigine**.

(emphasis added).

84. On April 4, 2005, the parties filed a Stipulation and Order of Dismissal in the Patent Litigation seeking the dismissal of all claims and counterclaims. On the same day the Court signed the dismissal, it also entered an order withdrawing the bench ruling that invalidated claim 1 of the '017 patent.

C. Teva's Exclusive Launch of Generic Lamotrigine Tablets.

85. Despite having received FDA approval to launch lamotrigine tablets almost two years earlier, Teva delayed launching its generic version of Lamictal Tablets until after the close of business on July 21, 2008 (the earliest date permitted under the terms of the Agreements with GSK).

86. Pursuant to the Agreements between GSK and Teva, GSK did not launch its own authorized generic of either Lamictal Tablets or Lamictal Chewables in competition with Teva prior to January 2009.

87. Although Teva has alleged in the subsequent litigation that GSK implemented a scheme to slow Teva's market penetration for its generic version of Lamictal Tablets, none of GSK's conduct had the effect of constraining or reducing the pricing of Teva's generic Lamictal Tablets during the exclusivity period in the same way that competition from an authorized generic would.

88. On information and belief, Teva's 180-day market exclusivity period enabled it to generate many millions of dollars of additional revenue at the expense of purchasers who would have paid lower prices for Teva's generic lamotrigine tablets had GSK launched an authorized generic.

89. Because of Teva's 180-day exclusivity on generic versions of Lamictal Tablets, which was secured by and through the anticompetitive Agreements at issue, no other generic was allowed to launch, and none in fact did launch, prior to January 22, 2009. By the end of January 2009, at least three other firms (*i.e.*, Mylan, Watson, and Dr. Reddy's) launched generic versions of Lamictal Tablets.

D. Defendants' Conduct Delayed Generic Competition and Enabled Defendants To Wrongfully Charge Supra-Competitive Prices for Lamotrigine Tablets and Lamotrigine Chewables.

90. Teva's 180-day exclusivity period for its generic version of Lamictal Tablets would have been triggered earlier if GSK and Teva had not agreed to delay entry of Teva's generic Lamictal Tablets product until July 22, 2008 because (a) absent the inducements GSK gave Teva, the settlement would have provided for an earlier entry of Teva's less expensive generic version of Lamictal Tablets; and/or (b) Teva would have launched its generic Lamictal Tablet product upon receipt of final FDA approval in August 2006, either "at-risk" or after successfully invalidating the asserted claims of the '017 patent (which was highly likely). Instead, because of the unlawful Agreements, Teva did not enter until July 2008, leaving their 180-day exclusivity in place and thereby blocking final FDA approval and entry of other generic versions of Lamictal Tablets until January 2009.

91. The Agreements between Teva and GSK guaranteed that Teva's generic exclusivity period for generic Lamictal Tablets would not be triggered by a final court decision before Teva received FDA approval of that ANDA, and provided Teva with the full 180 days of exclusive generic sales on that product.

92. The Agreements between Teva and GSK guaranteed that GSK would have three more years of exclusivity on the blockbuster Lamictal Tablet product with no generic competition for the entire patent term even though it was highly likely that the remaining patent claims would have been invalidated in 2005.

93. In exchange for Teva's delaying its launch of its generic version of the Lamictal Tablet until close of business on July 21, 2008, Teva secured: (1) the right to almost immediately launch a generic equivalent of the Lamictal Chewable product, which generated some limited profit for Teva, but created much smaller consumer savings and benefits than an earlier launch of the Lamictal Tablet product (*i.e.*, any consumer welfare generated by the earlier launch of generic lamotrigine chewables pales in comparison to the consumer harm created by the anticompetitive delay in entry of the generic lamotrigine tablets); (2) a guarantee on its ability to fully exploit its 180-day exclusivity period relating to its generic version of Lamictal Tablets; and (3) GSK's agreement not to compete with Teva by not marketing an authorized generic for both Lamictal Tablets and Lamictal Chewables until January 2009.

94. Defendants' unlawful conduct, therefore, delayed not only the launch of less expensive generic versions of Lamictal Tablets, but prevented GSK's launch of authorized generic products in competition with Teva's generic versions of Lamictal Tablets and Lamictal Chewables prior to January 2009.

95. Moreover, the Agreements between GSK and Teva which delayed Teva's launch of the generic Lamictal Tablets and guaranteed Teva's exclusivity period on that product without competition from a GSK authorized generic were not necessary for the settlement of the Patent Litigation and constitute ancillary restraint of trade.

VI. EFFECT ON INTERSTATE COMMERCE

96. At all material times, Lamictal Tablets and Lamictal Chewables, manufactured and sold by GSK, and generic versions of Lamictal tablets manufactured by Teva, were shipped across state lines and sold to customers located outside its state of manufacture.

97. During the relevant time period, in connection with the purchase and sale of Lamictal Tablets and Lamictal Chewables (and Teva's generic versions of those products), monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

98. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

VII. RELEVANT MARKET

99. Direct proof exists that GSK had monopoly power over the price of lamotrigine tablets and their AB-rated generic equivalents. Such direct evidence will include, *inter alia*: (a) manufacturers' and/or market-wide transactional data that will show a significant, non-transitory decline in lamotrigine tablet prices upon entry of AB-rated generic lamotrigine tablets that had not occurred until generic entry; and (b) abnormally high price-cost margins enjoyed by GSK prior to the entry of such generic

competition. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether GSK had monopoly power.

100. Even at their monopoly price, Lamictal Tablet products do not exhibit significant, positive cross-elasticity of demand with respect to price with any products other than AB rated generic versions of Lamictal Tablets.

101. Lamotrigine Tablets – *i.e.* Lamictal Tablets (in all its forms and dosage strengths), and AB-rated equivalent lamotrigine tablets – constitute a separate and distinct product market. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by GSK's ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which lamotrigine tablets are prescribed.

102. At all relevant times, GSK enjoyed high barriers to entry with respect to the above-defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

103. Through the anticompetitive conduct alleged herein, Defendants were able to profitably charge supra-competitive prices for lamotrigine tablet products without losing substantial sales, and thus, by definition, maintained monopoly power with respect to lamotrigine tablet products sold in the United States.

104. GSK's market share in the relevant market was 100% until the entry of AB-rated generics.

105. Lamotrigine chewable products – *i.e.*, Lamictal Chewables (in all its forms and dosage strengths), and AB-rated equivalent lamotrigine chewable products – constitute a separate and distinct relevant product market. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by GSK's ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which lamotrigine chewables are prescribed.

106. At all relevant times, there have been high barriers to entry with respect to the above-defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

107. Through the anticompetitive conduct alleged herein, Defendants were able to profitably charge supra-competitive prices for lamotrigine chewable products.

VIII. FIRST CAUSE OF ACTION
VIOLATION OF SECTION 1 OF THE SHERMAN ACT
(15 U.S.C. §1)
(CONSPIRACY TO DELAY GENERIC COMPETITION FOR LAMICTAL TABLETS)

108. Plaintiffs incorporate and re-allege 1 to 107 of the foregoing Paragraphs herein, as though fully set forth below.

109. Beginning in or about February 2005 and continuing through January 2009, GSK and Teva engaged in a continuing illegal contract, combination and

conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of lamotrigine tablets in the United States to GSK until July 21, 2008; (b) fix the price at which Plaintiffs and the other members of the Class would pay for lamotrigine tablets at the higher, branded price during that period; and (c) prevent the sale of generic versions of lamotrigine tablets other than Teva's (including GSK's authorized generic versions) in the United States until at least January 22, 2009.

110. GSK's agreement to not launch its own authorized generic Lamictal Tablets before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic Lamictal Tablet. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

111. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' Agreements are horizontal market allocation and price fixing agreements between actual or potential competitors and thus are *per se* violations of Section 1. In the alternative, Defendants' Agreements are unreasonable restraints of trade

in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.

112. Plaintiffs and all members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiffs and the Class members have paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Tablets and/or Teva's generic equivalent.

113. As a result of Defendants' illegal conduct, Plaintiffs and the Class paid more than they would have paid for lamotrigine tablets, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing AB-rated generic versions of lamotrigine tablets well before July 2008 (including GSK through the launch of an authorized generic), and/or would have been able to market such versions more successfully.

114. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including GSK through the launch of an authorized generic), Plaintiffs and other Class members would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine requirements, and/or would have paid lower prices on some or all of their remaining purchases of GSK's Lamictal Tablets and/or Teva's generic equivalent**.**

115. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Lamictal Tablets directly from GSK and/or their

generic equivalent directly from Teva. As a result of the Defendants' illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet requirements. Plaintiffs and the other Class members paid prices for lamotrigine tablets that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Class members were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of brand-name Lamictal Tablets was artificially inflated by Defendants' illegal conduct.

IX. SECOND CAUSE OF ACTION
VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. §1)
(CONSPIRACY NOT TO COMPETE WITH GENERIC LAMICTAL TABLETS)

116. Plaintiffs incorporate and re-allege 1 to 107 of the foregoing Paragraphs herein, as though fully set forth below.

117. Beginning in or about February 2005 and continuing through January 2009, GSK and Teva engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, in which GSK agreed to not sell its competing authorized generic version of lamotrigine tablets until at least January 22, 2009.

118. As alleged above, as of 2005, GSK had a history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. Moreover, while GSK's use of DAW5 codes and discounts to certain retailers did not significantly constrain or reduce

the price of Teva's generic Lamictal Tablets, the fact that GSK used DAW5 discounts to ineffectively compete against Teva's generic Lamictal Tablets evidences that GSK was motivated, but for the anticompetitive Agreements, to price compete against Teva's generic product. Consequently, but for Defendants' illegal conduct, GSK would have sold its authorized generic version of Lamictal Tablets starting in July 2008 (or earlier if Teva had started selling its generic version of Lamictal tablets earlier).

119. GSK's agreement to not launch its own authorized generic Lamictal Tablets before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic versions of Lamictal Tablets. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

120. By entering into this unlawful conspiracy, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' Agreement is a horizontal market allocation agreement between actual or potential competitors and thus are *per se* violations of Section 1. In the alternative, Defendants' Agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.

121. Defendants' agreement that GSK would not launch an authorized generic version of Lamictal Tablets until after January 2009 did not constitute GSK's unilateral exercise of any legitimate patent power. As an initial matter, GSK's decision not to launch an authorized generic was not the result of GSK's unilateral decision but one that was made at a rivals' request as consideration for the rivals' agreement to stay off the market until July 2008. Furthermore, GSK's collusive agreement to constrain how it competed against Teva was not an exercise of any patent power GSK had to exclude Teva, but rather GSK's agreement to exclude its own generic product that it would have otherwise sold. Thus, the agreement has nothing to do with whether or how GSK exercised its patent powers but its agreement to limit its ability/willingness to compete. Moreover, the agreement that GSK would not launch an authorized generic to compete against Teva encompassed the period from July 2008 through January 2009, after the '017 patent had expired and during a period in which no other GSK exclusivities barred Teva from the market. So pursuant to the illegal agreement, GSK withheld its authorized generic from the market during a period that was outside the temporal scope of the '017 patent and/or any other exclusivities that applied to Teva.

122. Plaintiffs and all members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination, and conspiracy. Plaintiffs and the Class members have paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Tablets and/or Teva's generic equivalents.

123. As a result of Defendants' illegal conduct, Plaintiffs and the Class paid more than they would have paid for lamotrigine tablets, absent Defendants' illegal conduct. Had GSK launched an authorized generic version of Lamictal Tablets (as it was motivated to do), Plaintiffs and other Class members would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine requirements, and/or would have paid lower prices on some or all of their remaining purchases of GSK's Lamictal and/or Teva's generic equivalents.

124. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Lamictal Tablets directly from GSK and/or their generic equivalent directly from Teva. As a result of the Defendants' illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet. Plaintiffs and the other Class members paid prices for lamotrigine tablets that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Class members were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of brand-name Lamictal Tablets were artificially inflated by Defendants' illegal conduct.

X. THIRD CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT AGAINST GSK
(15 U.S.C. § 2)
(MONOPOLIZATION OF LAMICTAL TABLETS MARKET)

125. Plaintiffs incorporate and reallege 1 to 107 of the foregoing Paragraphs in this Complaint, as though fully set forth below.

126. Defendant GSK used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend its monopoly power in the lamotrigine tablet market, as detailed above.

127. GSK combined, conspired and contracted with Teva to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and GSK did in fact monopolize trade in the United States in the market for lamotrigine tablets, and to eliminate competition in the sale of Lamictal Tablets and their generic equivalents in the United States.

128. The goal, purpose and/or effect of GSK's scheme was also to maintain and extend GSK's monopoly power with respect to lamotrigine tablets. GSK's illegal scheme to prevent, delay and/or minimize the success of the introduction into the United States marketplace of any generic version of Lamictal Tablets enabled GSK to continue charging supra-competitive prices for lamotrigine tablets without a substantial loss of sales.

129. GSK's agreement to not launch its own authorized generic Lamictal Tablets before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic Lamictal Tablets. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry for generic versions of Lamictal Tablets, GSK had no financial or

economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

130. As a result of GSK's illegal conduct, Plaintiffs and the Class paid more than they would have paid for lamotrigine tablets, absent GSK's illegal conduct. But for GSK's illegal conduct, competitors would have begun marketing AB-rated generic versions of Lamictal Tablets well before July 2008 (including GSK through the launch of an authorized generic), and/or would have been able to market such versions more successfully.

131. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including GSK through the launch of an authorized generic), Plaintiffs and other Class members would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine tablet requirements, and/or would have received lower prices on some or all of their remaining purchases of GSK's Lamictal Tablets and/or Teva's generic equivalents.

132. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Lamictal Tablets directly from GSK and/or their generic equivalents directly from Teva. As a result of GSK's illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet requirements. Plaintiffs and all of the other Class members paid prices for lamotrigine tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower priced

generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Class members were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of branded Lamictal Tablets were artificially inflated by GSK's illegal conduct.

133. GSK's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for lamotrigine tablets in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

XI. FOURTH CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT
(15 U.S.C. § 2)
(CONSPIRACY TO MONOPOLIZE LAMICTAL TABLETS MARKET)

134. Plaintiffs incorporate and reallege 1 to 107 and 125 to 133 of the foregoing Paragraphs in this Complaint, as though fully set forth below.

135. GSK and Teva combined, conspired and contracted with Teva to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and GSK and Teva did in fact conspire to monopolize trade in the United States in the market for lamotrigine tablets, and to eliminate competition in the sale of Lamictal Tablets and their generic equivalents in the United States.

136. The goal, purpose and/or effect of GSK and Teva's conspiracy was also to maintain and extend GSK's monopoly power with respect to lamotrigine tablets. GSK and Teva's illegal conspiracy to prevent, delay and/or minimize the success of the introduction into the United States marketplace of any generic version of Lamictal Tablets enabled GSK to continue charging supra-competitive prices for lamotrigine tablets without a substantial loss of sales.

137. GSK and Teva committed overt acts in furtherance of the conspiracy including, *inter alia*, GSK's agreement to not launch its own authorized generic Lamictal Tablets before January 2009, which was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation and to get Teva to agree to delayed entry dates for its generic Lamictal Tablet. GSK believed it would be profitable to launch its own authorized generic Lamictal Tablets, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Tablets before January 2009 and it would not have done so.

138. As a result of GSK and Teva's illegal conduct, Plaintiffs and the Class paid more than they would have paid for lamotrigine tablets, absent Defendants' illegal conduct. But for GSK and Teva's illegal conduct, competitors would have begun marketing AB-rated generic versions of Lamictal Tablets well before July 2008 (including GSK through the launch of an authorized generic), and/or would have been able to market such versions more successfully.

139. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including GSK through the launch of an authorized generic), Plaintiffs and other Class members would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine tablet requirements, and/or

would have received lower prices on some or all of their remaining purchases of GSK's Lamictal Tablets and/or Teva's generic equivalents.

140. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Lamictal Tablets directly from GSK and/or their generic equivalents directly from Teva. As a result of GSK and Teva's illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet and lamotrigine chewable requirements. Plaintiffs and all of the other Class members paid prices for lamotrigine tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Class members were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of branded Lamictal Tablets were artificially inflated by GSK and Teva's illegal conduct.

141. GSK and Teva's illegal conduct had an affect on interstate commerce as alleged in paragraphs 96 to 98 above.

142. GSK and Teva's conduct was in the aggregate a conspiracy undertaken with the specific intent to monopolize the market for lamotrigine tablets in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

XII. FIFTH CAUSE OF ACTION
VIOLATION OF SECTION 1 OF THE SHERMAN ACT
(15 U.S.C. §1)
(CONSPIRACY NOT TO COMPETE WITH GENERIC LAMICTAL CHEWABLES)

143. Plaintiffs incorporate and re-allege 1 to 107 of the foregoing Paragraphs herein, as though fully set forth below.

144. Beginning in or about February 2005 and continuing through January 2009, GSK and Teva engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, in which GSK agreed to not sell its competing authorized generic version of lamotrigine chewables until at least January 22, 2009.

145. As alleged above, as of 2005, GSK had a history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. Moreover, while GSK's use of DAW5 codes and discounts to certain retailers did not significantly constrain or reduce the price of Teva's generic Lamictal Tablets, the fact that GSK used DAW5 discounts to ineffectively compete against Teva's generic Lamictal Tablets evidences that GSK was motivated, but for the anticompetitive Agreements, to price compete against Teva's generic product. Consequently, but for Defendants' illegal conduct, GSK would have sold its authorized generic version of Lamictal Chewables starting in June 2006 (or earlier if Teva had started selling its generic version of Lamictal Chewables earlier).

146. GSK's agreement to not launch its own authorized generic Lamictal Chewables before January 2009 was not a legitimate independent, self-standing, bona fide business transaction. As Teva has admitted, GSK agreed to the provision to induce Teva to relinquish the rights and defenses it was asserting against GSK in the Patent

Litigation and to get Teva to agree to delayed entry dates for its generic versions of Lamictal Tablets and Lamictal Chewables. GSK believed it would be profitable to launch its own authorized generic Lamictal Chewables, as evidenced by GSK's long-standing practice of launching such authorized generic products. Thus, aside from inducing Teva to agree to relinquish its patent defenses and delay its market entry, GSK had no financial or economic interest in agreeing to not launch its own authorized generic Lamictal Chewables before January 2009 and it would not have done so.

147. By entering into this unlawful conspiracy, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' Agreement is a horizontal market allocation agreement between actual or potential competitors and thus are *per se* violations of Section 1. In the alternative, Defendants' Agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.

148. Defendants' agreement that GSK would not launch an authorized generic version of Lamictal Chewables until after January 2009 did not constitute GSK's unilateral exercise of any legitimate patent power. As an initial matter, GSK's decision not to launch an authorized generic was not the result of GSK's unilateral decision but one that was made at a rivals' request as consideration for, among other things, the rivals' agreement to stay off the market for more than three months on the Lamictal Chewables product. Furthermore, GSK's collusive agreement to constrain how it competed against Teva was not an exercise of any patent power GSK had to exclude Teva, but rather GSK's agreement to exclude its own generic product that it would have otherwise sold. Thus, the agreement has nothing to do with whether or how GSK exercised its patent

powers but its agreement to limit its ability/willingness to compete. Moreover, the agreement that GSK would not launch an authorized generic to compete against Teva encompassed the period from at least June 2006 through January 2009, after the '017 patent had expired and during a period in which no other GSK exclusivities barred Teva from the market. So pursuant to the illegal agreement, GSK withheld its authorized generic from the market during a period that was outside the temporal scope of the '017 patent and/or any other exclusivities that applied to Teva.

149. Plaintiffs and all members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination, and conspiracy. Plaintiffs and the Class members have paid more for their purchases of Lamictal Chewables and/or Teva's generic lamotrigine chewables than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Chewables and/or Teva's generic equivalents.

150. As a result of Defendants' illegal conduct, Plaintiffs and the Class paid more than they would have paid for lamotrigine chewables, absent Defendants' illegal conduct. Had GSK launched an authorized generic version of Lamictal Chewables (as it was motivated to do), Plaintiffs and other Class members would have substituted lower-priced generic lamotrigine chewables for the higher-priced brand-name Lamictal Chewables for some or all of their lamotrigine requirements, and/or would have paid lower prices on some or all of their remaining purchases of GSK's Lamictal Chewables and/or Teva's generic equivalents.

151. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Lamictal Chewables directly from GSK and/or their generic equivalent directly from Teva. As a result of the Defendants' illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their lamotrigine chewable requirements. Plaintiffs and the other Class members paid prices for lamotrigine chewables that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic lamotrigine chewables instead of expensive brand-name Lamictal Chewables; (2) Class members were forced to pay artificially inflated prices for generic lamotrigine chewables; and/or (3) the price of brand-name Lamictal Chewables were artificially inflated by Defendants' illegal conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of itself and the proposed Class, prays for judgment against all Defendants, jointly and severally, as follows:

1. That the Court adjudge and decree that the Defendants and each of them have violated Sections 1 and 2 of the Sherman Antitrust Act;

2. That the Plaintiffs and all others similarly situated be awarded damages suffered by reason of these violations and that those damages be trebled in accordance with the law;

3. That the Plaintiffs be awarded reasonable attorneys' fees and costs;

4. That any and all rights that Teva may have under the Hatch-Waxman Act be declared null and void and of no further effect; and

5. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims and complaints in this Complaint so triable.

DATED: June 25, 2012

Respectfully submitted,

s/ Peter S. Pearlman

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